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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,211	06/08/2005	Yasuo Suzuki	2005_0700A	6772
513 7590 10/23/2007 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER BOESEN, AGNIESZKA	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 10/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,211	Applicant(s) SUZUKI ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5, 7, 8 and 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/8/2005 and 4/22/2005</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) <input type="checkbox"/> Notice of Informal Patent Application
6) <input type="checkbox"/> Other: _____. |
|--|---|

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received August 28, 2007.

Election/Restrictions

Applicant's election without traverse of group IV, claim 6, is acknowledged. Claims 4, 5, 7, 8, 10-12, and new claims 13-19 are withdrawn because the claims are drawn to the non-elected invention. Claim 6 and linking claims 1-3 are under examination in the present Office action.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 22, 2005 and August 8, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the essential labels required to read the figures as described in the specification. Particularly, Figure 5 lacks the essential information with regard to the concentrations of the paragloboside as described in the specification on page 24, and Figure 6 lacks the information with regard to the content of the wells in a gel as well as the concentrations of the paraglobocide as described in the specification on page 26. It is also noted that Figures 1-4, 7, and 8 also lack essential information

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critical to reading the figures. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Claim 3 recites the limitation “Hex³” and “Hex³Nac”. There is insufficient antecedent basis for this limitations in the claim, because the formula I in claims 1 and 2 does not recite “Hex³” or “Hex³Nac”.

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1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make, and/or use the invention.

The claims are drawn to a dengue virus infection inhibitor characterized by containing a carbohydrate molecule having an oligosaccharide chain represented by the formula: (Hex-NAc β 1-3Hex β 1-4Hex β 1)_n- conjugated to various substrates. The claims are rejected because the specification does not provide a sufficient enabling disclosure for the claimed dengue virus infection inhibitors represented by a carbohydrate formula encompassing a large number of carbohydrates conjugated to various substrates. The specification does not provide sufficient enablement for the claimed dengue virus inhibitors wherein the virus infection is inhibited *in vivo* in an animal.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the

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claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors deemed relevant are those of the amount of direction and the working examples provided, that quantity of experimentation necessary, the (un)predictability of the art, and the breadth of the claims.

The claims are broadly drawn to a carbohydrate structure, which intended use is to inhibit dengue virus infection. The claims encompass inhibiting dengue virus infection both *in vitro* and *in vivo*. The claimed formula Hex-NAc β 1-3Hex β 1-4Hex β 1)_n- encompasses a number of various carbohydrate structures because a hexose broadly reads on a monosaccharide with six carbon atoms, and represents a genus of at least eight different monosaccharides, for example, glucose, mannose, galactose, allose, altrose, talose, and idose.

In support of the present claims, the specification provides working examples discussing screening the activity of a species of the claimed inhibitor, represented by a formula Gal β 1-4GlcNAc β 1-3Gal β 1-Glc β 1-1 Ceramide, on dengue virus infecting K562 cells in a cell culture (Examples 2 and 3). The specification does not provide working examples with regard to other carbohydrate species encompassed by the claims. The specification does not provide working examples with regard to the *in vivo* activity of the claimed carbohydrates. As discussed above, the drawings submitted by Applicants are difficult to read because they lack essential information required to understand the experimental results disclosed in the specification. Therefore, the Office is unable to properly understand the disclosed invention.

The art teaches identification of carbohydrate molecules in mammalian cells recognized by dengue virus type 2. Aoki et al. (Journal of Biochemistry, 2006, Vol. 139, p. 607-614) teach marginal effects of the carbohydrate molecules comprising Gal β 1-4GlcNAc β 1-3Gal β 1-Glc β 1-1

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on dengue virus infection of BHK-21 cells. There is lack of a teaching in the art showing that carbohydrates can be successfully used to inhibit dengue virus infection *in vivo* in an animal.

The skilled artisan would be required to conduct an undue amount of experimentation in order to determine if the claimed carbohydrate structures could be successfully used as dengue virus infection inhibitors in humans. Thus in view of the limited working examples in the specification, the lack of supportive teachings in the art, the breadth of the claims and the amount of the experimentation required to determine if the claimed carbohydrate molecules can be successfully used as dengue virus infection inhibitors, it is determined that Applicant's disclosure lacks sufficient enablement for the claimed inhibitors.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Karlsson et al. (US Patent 4,859,769).

Claims are drawn to a dengue virus infection inhibitor characterized by containing a carbohydrate molecule having an oligosaccharide chain represented by the formula: Gal β 1-4GlcNAc β 1-3Gal β 1-Glc β 1-. The claims are also drawn to a dengue virus infection inhibitor containing the formula (Gal β 1-4GlcNAc β 1-3Gal β 1-Glc β 1)_n-R, wherein R is a lipid.

Karlsson discloses antiviral agents containing a carbohydrate molecule having an oligosaccharide chain represented by the formula Gal β 1-4GlcNAc β 1-3Gal β 1-Glc β 1- (see the

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entire document, specifically for the formula see column 12, line 50). Karlsson discloses $(\text{Gal}\beta 1\text{-}4\text{GlcNAc}\beta 1\text{-}3\text{Gal}\beta 1\text{-Glc}\beta 1)_n\text{-R}$, wherein R is a lipid. Karlsson discloses that the $\text{Gal}\beta 1\text{-}4\text{GlcNAc}\beta 1\text{-}3\text{Gal}\beta 1\text{-Glc}\beta 1$ and other oligosaccharides conjugated to lipids have the ability to bind to a site on the virus, which recognizes the binding epitope of the natural viral receptor on a target cell, and thereby inhibit virus entry into the cell (see column 15, lines 20-46). Karlsson does not disclose the oligosaccharides inhibiting dengue virus infection. However the limitation of “a dengue virus infection inhibitor” is viewed as an intended use and is thus not considered limiting for the purpose of the present rejection.

Thus because Karlsson disclose the presently claimed carbohydrate formulas, Karlsson anticipate the present claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 10-19-2007
Primary Examiner, TC1600